A GUIDE FOR EMPLOYERS

Using Comparative Effectiveness Research

JUNE 2011

National Business Group on Health

Treatments for Clinically Localized Prostate Cancer

This guide provides actions suggested by the National Business Group on Health for employers who want to use comparative effectiveness research (CER) in their health plan and program design. It is based on research funded by the federal Agency for Healthcare Research and Quality (AHRQ). See the "Resources" section at the end of this guide for patient information on the treatment of prostate cancer.

Impact on Employers

Prostate cancer is very common, with one in six men developing it over their lifetime. The risk increases with age, as 4 out of 5 cases are diagnosed in men over age 65, and only 1% of cases are found in men under age 50. Ninety percent of the men diagnosed have localized prostate cancer or cancer that has not spread outside the prostate gland. Typically, localized prostate cancer is very slow-growing and often causes no harm during the patient's lifetime. However, some cases can spread more rapidly and require active treatment.

Screening with the PSA blood test to detect prostate cancer has increased over the last decade, and so too has the number of cancers detected and the number of men undergoing active treatment. However, treatments can pose challenges in some cases due to problematic side effects. Men with prostate cancer should weigh carefully what treatment is appropriate to their situation. Often the best treatment is "active surveillance," which allows an employee to learn more about their cancer, whether it has spread, and if active treatment is required. Employers have an interest in helping men work with their doctors to make treatment decisions based on medical evidence and individual circumstances and preferences.

Deciding on Treatment

After receiving a prostate cancer diagnosis, a man faces two decisions. The first is whether to wait and see if the cancer progresses (expectant management) or to treat it right away. Since most prostate cancer grows slowly, expectant management is a common choice. It provides time to learn what the options are and avoid the side effects of active treatment.

The second decision comes when active treatment is chosen. The most common active treatments are radical prostatectomy and radiation therapy. All active treatments have side effects that may be long-lasting, including sexual, urinary and bowel problems.

Agency for Healthcare Research & Quality

Comparative Effectiveness Research Findings

In 2008, the AHRQ Effective Healthcare Program funded a review of research literature which examined evidence on the effectiveness and safety of treatments for clinically localized prostate cancer. The following findings are based upon this review, entitled *Comparative Effectiveness of Therapies for Clinically Localized Prostate Cancer* (2008), which resulted in the publication of consumer and clinician guides in July 2008.

AHRQ-funded researchers compared the effectiveness and safety of four common treatments for clinically localized prostate cancer: expectant management, prostate surgery, radiation therapy and hormonal therapy. The research did not cover nutritional supplements. Data were not sufficient to address newer treatments such as cryotherapy, high-intensity focused ultrasound, and laparoscopic or robotic-assisted prostatectomy.

What is a Gleason Score?

The Gleason Grading System helps to evaluate the prognosis of men with prostate cancer. The score is determined from a tissue biopsy. Gleason scores range from 2 to 10, with a lower score (2-5) indicating the cancer will likely grow slowly. Tumors with higher Gleason scores (8-10) are considered aggressive and are likely to spread outside the prostate gland within five years. Researchers found that men with higher scores have higher rates of cancer recurrence and death than men with lower scores, regardless of the treatment.

Main research findings:

Research has not determined which treatment option is best for localized prostate cancer. All active therapies can cause temporary and permanent side effects. Therefore, men should work with their doctors to make decisions based on individual circumstances and preferences. Factors weighed when deciding on treatment include age, health status, PSA level, Gleason score (assessment of the cancer's aggressiveness, see sidebar), and individual preferences.

Treatment approaches are found to vary by geographic region and physician specialty. Hospitals and surgeons that do more surgeries have better results.

Treatment Options and Findings

Expectant management, also called watchful waiting or active surveillance, means to carefully watch the cancer over time with regular physician visits and exams such as a digital rectal exam, PSA blood test, prostate ultrasound and biopsy.

Finding:
A common choice, expectant management gives the patient time to learn about treatment options. Based on the main research finding, its primary advantage is not prematurely choosing a treatment that could have harmful side effects.

Prostate surgery, also known as radical prostatectomy, removes the prostate gland and cancer within the gland, along with the portion of the urethra surrounded by the prostate gland. The rest of the urethra is reattached to the bladder.

Findings:

- The risks of prostate surgery increase with age, with up to 10 out of 100 men 65 years and older experiencing heart and lung problems after surgery.
- Incontinence is more common after surgery than after radiation or hormone therapy.
- Men treated in hospitals that do 43 or more prostatectomies each year have fewer complications than men treated in hospitals that perform fewer prostatectomies.
- Men treated by surgeons that do ten or more prostatectomies per year have lower rates of urinary complications and incontinence than men treated by surgeons who do fewer prostatectomies.
- There is not enough evidence to know whether newer surgical techniques, such as laparoscopy or robotic-assisted surgery, are as effective as conventional surgery.

The Decision to Have a PSA Test

Prostate specific antigen (PSA) screening is a blood test used to detect prostate cancer early. The U.S. Preventive Services Task Force (USPSTF) found insufficient medical evidence to assess the balance of benefits and harms of prostate cancer screening in men younger than 75 years, and recommends against screening for prostate cancer in men 75 years and older. Most medical organizations recommend that men over 50 discuss the potential benefits and harms of PSA screening with their doctors.

Radiation therapy, performed in a hospital or clinic, delivers radiation to the cancer cells. External Beam Radiation Therapy (EBRT) is given over multiple days; whereas with brachytherapy, radioactive seeds placed within the prostate release radiation over time.

Findings:

- Higher doses of radiation slow the rate of cancer progression compared with lower doses of radiation, but may be associated with increased rates of gastrointestinal side effects. Whether the lower rate of cancer progression will translate into improved survival or quality of life is not known.
- There is not enough evidence to determine whether higher doses of radiation reduce mortality compared to lower doses.
- There is not enough evidence to determine whether the outcomes of other radiation therapies (brachytherapy, proton beam or intensity-modulated radiation therapy) differ from outcomes of conventional EBRT.

Hormonal therapy, given by injection or medication, lowers or blocks testosterone, a hormone that causes prostate cancer cells to grow. Typically, hormone therapy is used in combination with another active treatment, although occasionally it is used alone.

Findings:

- Hormone therapy before prostate surgery does not improve survival or recurrence rates compared to surgery alone.
- Hormone therapy can cause loss of libido, depression, memory difficulties, fatigue, hot flashes, gynecomastia (abnormal breast development in males) and bone fractures.

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Strategies for Employers

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Employers can help their employees and dependents get evidence-based care by using the following strategies:

- Make patient decision aids, including information on providers, easily accessible to employees;
- Work with health carriers to carefully manage the use of treatments that—
  - Have no demonstrated evidence of effectiveness,
  - Are provider- or supply-sensitive, or
  - Are newer and more expensive, but not necessarily better than other treatments.

Patient Decision Aids

The evidence shows that decision aids work best when there is more than one medically appropriate option and none has a clear advantage, which is the case for localized prostate cancer.

Decision aids range from high touch, such as consultations between patient and doctor, to high tech, such as online interactive web modules. Some decision aids are offered by health plans, while others are available by contract with independent vendors or free from federal agencies.

The challenge is getting employees to use these helpful tools. Here are some tactics to engage them:

- Target communications to men over age 50 and use every available channel such as home mailings, workplace materials, health plan communications and intranet newsletters.
- Use plan design tactics such as a notification requirement for prostate cancer treatments or reduced employee cost-sharing when decision-support tools and services are used.
- Provide incentives such as cash or gift cards for using decision-support tools and services.

See the table on the next page for prostate cancer decision-support information, tools and services. Although many of these products are used by National Business Group on Health members, this is not intended as an endorsement, nor is it a complete list of all such services.

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Patient Decision Aids for Localized Prostate Cancer

AHRQ Effective Healthcare Program http://www.effectivehealthcare.ahrq.gov	Free guide available online with a summary of research on localized prostate cancer treatments and questions to help men talk with their doctors about options.
Best Doctors http://www.bestdoctors.com	Employers contract with Best Doctors to provide employees with expert medical consultations and a comprehensive review of diagnosis and treatment options.
Consumer's Medical Resource http://www.consumersmedical.com	Employers contract with CMR to provide employees with a comprehensive overview of their condition, treatment options with available effectiveness and outcomes data, and lifestyle information. The service also helps patients choose the best hospitals and providers.
Foundation for Informed Medical Decision Making http://www.informedmedicaldecisions.org	The Foundation produces Shared Decision Making ® tools by combining systematic reviews of the science and evidence with information from patient focus groups and interviews about patient perspectives. If the patient does not have access to Health Dialog services, they may request a review copy of the decision tool from the Foundation.
Health Dialog http://www.healthdialog.com	Employers contract with Health Dialog, to give employees access to the Shared Decision-Making® programs including personal health coaching.
National Comprehensive Cancer Care Network (NCCN) Guidelines for Patients: Prostate Cancer http://nccn.com/images/patient-guidelines/pdf.prostate.pdf	A free guide that provides cancer patients with information on treatment in easy-to-understand language as well as information designed to assist communication with a doctor about treatment options.

Treatment costs are often not included in decision support tools. However, patients will bear a portion of the cost and may want that information. Men should feel comfortable asking their provider about treatment cost. A study published in 2010 using Medicare data shows the average cost of the various treatments (see table on right).

Prostate Cancer Treatment Costs

Treatment	Five-Year Total
Watchful Waiting	$9,130
Radiation Therapy Only	$15,589
Hormonal Therapy	$26,896
Hormonal Therapy plus Radiation	$25,097
Surgery	$19,214

Source: Claire F. Snyder, Kevin D. Frick, Amanda L. Blackford, Robert J. Herbert, Bridget A. Neville, Michael A. Carducci, and Craig C. Earle. **How does initial treatment choice affect short-term and long-term costs for clinically localized prostate cancer?** *Cancer*, 2010.

Monitoring the Use of New Treatments

As new and modified treatments become available, it's important for employers to keep in mind that not all of them have shown their effectiveness and/or a cost-benefit. For example, employers and health plans are keeping an eye on the use of intensity modulated radiation therapy (IMRT). A modification of EBRT, it targets radiation more precisely to minimize damage to surrounding tissue.

The use of IMRT, which is much more costly than other localized prostate cancer treatments, has increased rapidly in recent years, possibly because a growing number of urology groups have IMRT capabilities. A 2010 analysis of Medicare billing data found an estimated $1 billion spent on IMRT, with much of it for prostate cancer. Payments per patient ranged up to $40,000. In contrast, Medicare pays up to $16,000 for surgery to remove the prostate and $19,000 for brachytherapy.

IMRT may be appropriate for some patients who choose radiation therapy. But employers working with their health carriers may want to guard against self-referrals that can lead to IMRT overuse. Employers can ask their data warehouse vendors or health carriers to analyze treatment approaches by geographic region and physician specialty to uncover outliers.

Conclusion

Comparative effectiveness research has not determined which treatment option is best for localized prostate cancer. All active therapies can cause temporary and permanent side effects. Therefore, men should work with their doctors to make decisions based on individual circumstances and preferences. Employers working with their health vendors can support men to make informed decisions when choosing a treatment and provider.

Resources

Treating Prostate Cancer: A Guide for Men with Localized Prostate Cancer
Agency for Healthcare Research and Quality, July 2008.
This guide for patients and consumers can help men talk with their health care professionals about treatment options for prostate cancer.
http://www.effectivehealthcare.ahrq.gov

Questions are the Answer
Agency for Healthcare Research and Quality
Easy-to-use consumer website that helps patients take an active role in their health care by asking questions so that they understand their condition and options.
http://www.ahrq.gov/questionsaretheanswer/

For Free Print Copies of the Consumer and Clinician Guides

AHRQ Publications Clearinghouse – 800.358.9295
Treating Prostate Cancer: Consumer's Guide, AHRQ Pub. No. 08-EHC010-2A
Treatments for Clinically Localized Prostate Cancer: Clinician's Guide, AHRQ Pub. No. 08-EHC010-3

REFERENCES

Screening for Prostate Cancer: Recommendation Statement, August 2008, U.S. Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org/uspstf/uspsprca.htm, accessed on 2/14/11.

O'Connor et al, Decision aids for people who are facing health treatment and screening decisions. Cochrane Database of Systematic Reviews 2009, Issue 3, Article Number CD001431.

Carreyrou J, Tamman M. A Device to Kill Cancer, Lift Revenue. *The Wall Street Journal*, December 7, 2010.

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All materials are in the public domain. Additional copies of this *Guide* are available at www.businessgrouphealth.org or by contacting healthservices@businessgrouphealth.org for more information.

About the National Business Group on Health

The Business Group is the only non-profit organization devoted exclusively to representing large employers' perspectives on national health issues and providing solutions to its members' most important health care and health benefits challenges. The Business Group fosters the development of a safe health care delivery system and treatments based on scientific evidence. Members share strategies for controlling costs, improving patient safety and quality of care, increasing productivity and supporting healthy lifestyles.

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